

S

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

THE JOHNS HOPKINS UNIVERSITY, a : Case No. 94-105 RRM  
Maryland corporation, BAXTER :  
HEALTHCARE CORPORATION, a Delaware:  
corporation, and BECTON DICKINSON :  
AND COMPANY, a New Jersey corporation, :  
: Plaintiffs, :  
: :  
: v. :  
: :  
CELLPRO, INC., a Delaware corporation, :  
: :  
Defendant. :  
: :  
:

**DECLARATION OF DR. ROBERTSON PARKMAN**

DECLARATION OF DR. ROBERTSON PARKMAN

I, ROBERTSON PARKMAN, M.D., do hereby declare:

1. I am currently Head of the Division of Research Immunology/Bone Marrow Transplantation at Children's Hospital Los Angeles in Los Angeles, California and Associate Director for Clinical Research of Children's Hospital Research Institute at Children's Hospital Los Angeles. I am the overall director of the Bone Marrow Transplant Program at Children's Hospital, Los Angeles.
2. I have performed bone marrow transplants for over twenty-five years. I was involved in establishment of the Bone Marrow Transplant program at Children's Hospital, Boston and Brigham Women's Hospital. I established the Bone Marrow Transplantation program at Children's Hospital, Los Angeles in 1983 which has performed approximately 400 transplants at a rate of about 45 per year for immunological, genetic, hematological diseases and cancer, and 4-6 T cell depleted bone marrow transplants per year for treatment of SCID children. My curriculum vitae further detailing my professional, publications and educational experience is attached hereto as Exhibit A.
3. I have used the CellPro CEPRATE® SC stem cell concentrator in my clinical research since 1993. The focus of our research is in areas of genetic disease, including gene therapy for Gaucher

disease, ADA deficiency, and HIV. The Cellpro device is an integral part of this research effort since it enables us to isolate stem cells and to achieve a smaller volume of cells to be transduced and it enables us to reduce the volume of reagents used to transduce the cells. We currently have studies planned or underway with respect to patients with congenital severe combined immunodeficiency disease ("SCID") due to adenosine deaminase ("ADA") deficiency (causing an abnormality in T-cell and B-cell function), and studies with patients diagnosed prenatally or later with AIDS. In addition, we have an approved FDA protocol for in utero transplantation of fetuses diagnosed with alpha thalassemia, a congenital disorder in which there is a defect in the synthesis of a subunit of hemoglobin.

4. All of these clinical research studies have been or will be supported by funding through the NIH.

5. Speaking generally, the protocols we use in our research involve collecting cells from bone marrow, peripheral blood or cord blood; selecting stem cells using the CellPro device; and transducing these cells with normal DNA via vectors, in order to alter the genetic makeup of the cells. These cells are then transplanted into the patient. In theory, the transfected stem cells will then engraft into the patient and impart the desired attribute to the patient, i.e., to produce a particular enzyme in the case of ADA deficiency, or to become resistant to HIV.

6. These new research procedures offer significant potential improvements in the long term survival of these patients, without which they would have to resort to less than ideal conventional therapies. For example, the conventional treatment of ADA deficiency is to administer Peg ADA to the patient. The protocol enables us to transplant the patient's own transfected stem cells thereby avoiding the risk of any graft versus host disease associated with allogeneic transplantation or the need for the patient to receive life-long pharmacotherapy. Without stem cell selection methodologies, research in this area would cease.

7. CellPro's technology is of critical importance to our in utero (in the womb) transplantation program. This protocol was approved by the FDA one year ago and focuses on the efficacy of stem cell transplantation in fetuses who have been determined via genetic testing before birth, to have congenital diseases, including alpha thalassemia. In the protocol paternal stem cells would be transplanted in utero. Removal of T cells is essential when transplanting fetuses to avoid any risk of GVHD; therefore, the more pure the stem cell population the better. Accordingly, we are in the process of amending our protocol to include processing of paternal bone marrow with both the CEPRATE® device to select stem cells, and with CellPro's CD2 column to purge T cells. Transplantation of normal stem cells in utero offers several advantages over transplantation after birth, including lessening the risk of damage to the fetus caused by the disorder

prior to birth, and the ease and safety of the in utero environment providing the ideal isolation chamber for the fetus prior to engraftment. Without the CellPro devices, this protocol would not proceed.

8. I was asked what effect the inability to obtain the CellPro CEPRATE® device would have on our clinical research programs. With respect to the SCID and HIV gene therapy protocols, some amount of revision of our protocols would be necessary if we were forced to use another stem cell selection device. Moreover, it is not certain whether such devices would be available from other manufacturers for use in these protocols. And, as I have already stated, our in utero program would essentially be ended since I know of no other manufacturer that offers a system to stem cell select and T cell deplete. It is my opinion that the clear public benefit that would be at jeopardy if the CellPro product was removed from the market is in the context of mismatched bone marrow transplantation since stem cell selection is a way to T cell deplete the graft and avoid GVHD.

I declare under penalty of perjury that the foregoing is true and correct.

Executed at Los Angeles, California this 14<sup>th</sup> day of April 1997.

  
Robertson Parkman, M.D.

**CURRICULUM VITAE**  
**ROBERTSON PARKMAN, M.D.**

**A. PERSONAL INFORMATION**

Business Address: Division of Research Immunology/  
Bone Marrow Transplantation  
Childrens Hospital Los Angeles  
4650 Sunset Blvd., MailStop 062  
Los Angeles, CA 90027

Business Phone: (213) 669-2546

Home Address: 627 South Euclid Avenue  
Pasadena, CA 91106

Home Phone: (818) 578-0797

Date of Birth: November 14, 1938

Place of Birth: Pittsburgh, Pennsylvania

Citizenship: U.S.A.

Marital Status: Single

Social Security Number: 189-28-7202

**B. EDUCATION**

High School: 1956 - The Hill School  
Pottstown, Penn.

College: 1960 - A.B. (Organic Chemistry)  
Cum Laude  
Amherst College  
Amherst, Mass.

Medical School: 1965 - M.D. Yale University  
School of Medicine  
New Haven, Conn.